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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/578,845

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EXAMINER

THERKORN, ERNEST G

ART UNIT

PAPER NUMBER

1797

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/578,845	Applicant(s) SHIBATA, KEIKO	
	Examiner Ernest G. Therkorn	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-6 is/are pending in the application.
- 4a) Of the above claim(s) 4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,3,5 and 6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claims 2, 3, 5, and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. “supplying a first eluent and eluting contaminants” implies that the contaminants are removed by the first eluent. However, the first two full paragraphs of page 11 of the specification makes clear that contaminants are still present at the end of fractionation. As such, the phrase renders the claims indefinite.

Claims 2, 3, 5, and 6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. No support for “supplying a first eluent and eluting contaminants” can be found. The first two full paragraphs of page 11 of the specification make clear that contaminants are still present at the end of fractionation. As such, the claims are considered to be drawn to new matter.

Claims 2, 3, 5, and 6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. No support for “starting fractionating eluted solution when the concentration reaches a predetermined concentration.” Page 11, the first full paragraph does not state that fractionation is initiated by an eluent

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concentration responsive signal. As such, the claims are considered to be drawn to new matter.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 3, 5, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Matsushita (Japan Patent No. 56-089058) in view of PTO Translation No. 08-6627 of Matsushita (Japan Patent No. 56-089058) or Takamura (Japan Patent No. 6-94697) in view of PTO Translation No. 08-6644 of Takamura (Japan Patent No. 6-94697) in view of Snyder (Introduction to Modern Liquid Chromatography, John Wiley&Sons, Inc., New York, 1979, pages 662-686) and Overfield (U.S. Patent No. 5,076,909). Matsushita (Japan Patent No. 56-089058) and PTO Translation No. 08-6627 are considered to be a single reference. Takamura (Japan Patent No. 6-94697) and PTO Translation No. 08-6644 are considered to be a single reference. At best, the claims differ from either Matsushita (Japan Patent No. 56-089058) in view of PTO Translation No. 08-6627 of Matsushita (Japan Patent No. 56-089058) or Takamura (Japan Patent No. 6-94697) in view of PTO Translation No. 08-6644 of Takamura (Japan Patent No. 6-94697) in reciting increasing the polarity of the eluents. Snyder (Introduction to Modern Liquid Chromatography, John Wiley&Sons, Inc., New York, 1979, pages 662-686) discloses increasing polarity of the eluents enhances detection sensitivity, improves resolution, and decreases column deterioration. In addition,

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Snyder (Introduction to Modern Liquid Chromatography, John Wiley&Sons, Inc., New York, 1979, pages 662-686) on page 684 discloses that hexane and dichloromethane are an eluting pair to increase polarity for liquid solid liquid chromatography. Overfield (U.S. Patent No. 5,076,909) (Abstract, column 8, lines 27-45; and column 12, lines 32-36) discloses changing from a weak solvent to a strong solvent achieves superior separation for heteroaromatics. Overfield (U.S. Patent No. 5,076,909) (column 19, lines 18-51) discloses that use of an alcohol in the solvent used to dissolve the sample maintains the adsorption properties of the stationary phase. It would have been obvious to use increasing polarity in each of Matsushita (Japan Patent No. 56-089058) in view of PTO Translation No. 08-6627 of Matsushita (Japan Patent No. 56-089058) and Takamura (Japan Patent No. 6-94697) in view of PTO Translation No. 08-6644 of Takamura (Japan Patent No. 6-94697) because Snyder (Introduction to Modern Liquid Chromatography, John Wiley&Sons, Inc., New York, 1979, pages 662-686) discloses increasing polarity of the eluents enhances detection sensitivity, improves resolution, and decreases column deterioration and Overfield (U.S. Patent No. 5,076,909) (Abstract, column 8, lines 27-45; and column 12, lines 32-36) discloses changing from a weak solvent to a strong solvent achieves superior separation for heteroaromatics. With regard to claim 2, it would have been obvious to use the specific solvents because Snyder (Introduction to Modern Liquid Chromatography, John Wiley&Sons, Inc., New York, 1979, pages 662-686) on page 684 discloses that hexane and dichloromethane are an eluting pair to increase polarity for liquid solid liquid chromatography and Overfield (U.S. Patent No. 5,076,909) (column 19, lines 18-51) discloses that use of an

alcohol in the solvent used to dissolve the sample maintains the adsorption properties of the stationary phase.

The remarks urge patentability based upon the allegation that each of Matsushita (Japan Patent No. 56-089058) in view of PTO Translation No. 08-6627 of Matsushita (Japan Patent No. 56-089058) and Takamura (Japan Patent No. 6-94697) in view of PTO Translation No. 08-6644 of Takamura (Japan Patent No. 6-94697) disclose steps that are not recited by the instant claims. However, these additional steps are not precluded by the open format of the instant claims.

The remarks urge patentability based upon use of gradient elution. Page 663, lines 6-13 of Snyder (Introduction to Modern Liquid Chromatography, John Wiley&Sons, Inc., New York, 1979, pages 662-686) discloses that use of gradient elution is the textbook technique for separating complex samples. Page 663, lines 19-25 discloses that gradient elution, i.e., increasing polarity of the eluents, enhances detection sensitivity, improves resolution, and decreases column deterioration. Page 663, lines 26-28 discloses that gradient elution procedures "enormously increase the ability of LC (Liquid Chromatography) to handle difficult samples and to deal with unusual situations or requirements." This is supplemented by Overfield (U.S. Patent No. 5,076,909) (Abstract, column 8, lines 27-45; and column 12, lines 32-36) disclosing changing from a weak solvent to a strong solvent achieves superior separation for heteroaromatics.

The remarks urge that the claims recited more than merely use of gradient elution based upon reciting contaminants are eluted. However, the first two full paragraphs of page 11 of the specification makes clear that contaminants are present

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from the beginning of the elution and remain at the end of fractionation. This would appear to be exactly what happens in gradient elution. Each component is eluted in different bands. Some of the earlier eluting band are not of interest and are merely referred to as contaminants. After the components of interest are eluted, there still remain other components not of interest and these also are referred to as contaminants. As such, the claims are merely directed to gradient elution.

The remarks urge that the action may not be made final because of an obvious, inadvertent typographical error. Claim 5 is directed to identical subject matter as rejected claim 3. The subject matter is in each of the primary references. It would be obvious that claim 5 was inadvertently omitted from the rejection because claim 5 is directed to identical subject matter as rejected claim 3 and the subject matter is in each of the primary references.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication should be directed to E. Therkorn at telephone number (571) 272-1149. The official fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Ernest G. Therkorn/
Ernest G. Therkorn
Primary Examiner
Art Unit 1797

EGT
February 24, 2009